



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/511,926

06/28/2005

Herman Jacobus Blok

65959/42

7214

1912

7590

02/24/2009

AMSTER, ROTHSTEIN & EBENSTEIN LLP
90 PARK AVENUE
NEW YORK, NY 10016

EXAMINER

DOE, SHANTA G

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

02/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,926	Applicant(s) BLOK ET AL.	
	Examiner SHANTA G. DOE	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/28/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-18 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/18/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 17 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The incubation device for a system according to claim 1 as claimed in claim 17 does not further limit the device claimed in claim 1.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3, 9, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding claims 3, 9 and 16, the word "preferably" renders these claims indefinite because it is unclear whether the limitation(s) following the word are part of the claimed invention. See MPEP § 2173.05(d).

4. Regarding claim 15, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by

Art Unit: 1797

"or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1797

8. Claims 1, 3,4, 7 ,8 & 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tretiakov et al (WO 00/61797) in view of Balch et al. (US 6,331,441) and Sandstrom (US 6,567,163) .

Regarding claim 1, Tretiakov discloses a system for conducting bioassays, comprising a substrate plate(1) with a number of wells(2), and an incubation device (the rest of the numbers in fig 2 comprises the incubation device) for holding the plate, characterized in that the substrate plate comprises a microplate(1) with an array of wells(2) arranged in rows and columns, and in that the incubation device comprises an incubation chamber (space between the lid and heat block (4)where the microplate is contained) for holding the microplate and a cover(see page 6, fig 2 ((6), (7),&(8))) for sealing the incubation chamber, said incubation device having a heat block(4) with array of openings, each opening adapted to receive a well of the microplate, wherein a sealing gasket(8) is provided for individually sealing each well of the microplate (see abs., fig 1& 2 page 3, lines 15 -25, page 4,5,6). The Tretiakov reference fails to disclose the system for conducting a bioassay wherein at the bottom of each well is a microarray substrate having oriented flow- through channels.

Balch (US 6,331,441) discloses a microplate with a number of wells wherein at the bottom of each well is a microarray substrate (fig 1a, 4, 11,&15, col. 4 lines 5-64 especially lines 60-64 , col. 6 lines 10-17).

Sandstrom (US 6,567,163) discloses that it was known in the art at the time of the invention to have a microarray substrate be provided with oriented flow-through channels for the flow of chemical and reagent for the microarray preparation, hybridization, labeling and etc. (see col. 19 lines 53 – col. 20 line 49, especially col. 20 lines 31-49).

In view of Balch and Sandstrom, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the bottom of each well in the microplate of the Tretiakov reference comprise a microarray substrate as taught by Balch and further have the microarray substrate comprise flow-through channels as taught by Sandstrom since Balch discloses that such a modification would allow for multiplexed analysis by parallel processing of a large number of samples (see col. 4 lines 35-65) and Sandstrom discloses that having flow through channels allows for the flow of chemical, reagent and or sample in the microarray.

Regarding claim 3, the combination as applied to claim 1 above discloses the system according to claim 1, wherein the maximum thickness of the incubation device heat block corresponds with the depth of the wells of the microplate, wherein preferably the circumferential wall of each opening is adapted to contact the outer wall of a well of the microplate (see Tretiakov fig 2).

Additionally, even though the reference does not directly state that the maximum thickness of the incubation device heat block corresponds with the depth of the wells of the microplate, it would have been obvious to one having ordinary skill in the art at the

Art Unit: 1797

time of the invention to have the maximum thickness of the incubation device heat block correspond with the depth of the wells of the microplate, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable value involves only routine skill in the art.

Regarding claim 4, the combination as applied to claim 1 above discloses the system according to claim 3, wherein the wells of the microplate and the openings of the heat block are conically shaped (see Tretiakov page 3, lines 19-20).

Regarding claim 7, the combination as applied to claim 1 above discloses the system according to claim 1, wherein the cover is provided with a heating element (see Tretiakov page 6 lines 12 -14).

Regarding claim 8, the combination as applied to claim 1 above discloses the system according to claim 1, wherein the incubation device is provided with a heating element (see Tretiakov page 5 and 6).

Regarding claim 17, the combination as applied to claim 1 above discloses the incubation device for a system according to claim 1.

Art Unit: 1797

9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tretiakov et al (WO 00/61797) in view of Balch et al. (US 6,331,441) and Sandstrom (US 6,567,163) as applied to claim 1 above, and further in view of Goffe (US 5,958,763).

Regarding claim 2, the combination as applied to claim 1 above discloses the system according to claim 1 wherein the incubation device comprises a circumferential wall. However, the combination fails to disclose that a sealing gasket is provided on the upper side of said circumferential wall, said sealing gasket being adapted to sealingly engage the lower side of the microplate.

Goffe (US 5,958,763) discloses that it is known in the art to use a gasket within an incubator in order to form tight seals.

In view of Goffe, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the incubator of the combined reference comprise a sealing gasket provided on the upper side of said circumferential wall wherein said sealing gasket being adapted to sealingly engage the lower side of the microplate, since such a modification would eliminate the problem of air gap which results in extremely slow heating hence such a modification would improve heating.

10. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tretiakov et al (WO 00/61797) in view of Balch et al. (US 6,331,441) and Sandstrom (US

Art Unit: 1797

6,567,163) as applied to claim 1 above, and further in view of Horner et al (US 2,440,472).

Regarding claim 6, the combination as applied to claim 1 above discloses the system according to claim 1, However, the combination fails to disclose that the cover is transparent.

Horner (US 2,440,472) discloses that it is known in the art for an incubator to comprise a transparent cover (see col. 1 line 55 - col. 2 lines 1).

In view of Horner, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the cover of the combination be transparent, since such a modification would allow one to view the contents within the incubator without having to open the incubator.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tretiakov et al (WO 00/61797) in view of Balch et al. (US 6,331,441) and Sandstrom (US 6,567,163) as applied to claim 1 above, and further in view of the applicant admitted prior art(APA).

Regarding claim 9, the combination as applied to claim 1 above discloses the system according to claim 1. The combination fails to specifically disclose that the substrate is made of a metal oxide, preferably an aluminium oxide.

The applicant admits that it is known in the art for an array substrate to be made of a metal oxide such as aluminium oxide (see applicant's current application [0002]).

In view of the applicant admitted prior art, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the substrate of the combined reference be made of metal oxide, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice

12. Claims 10, 12, 14 & 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch et al. (US 6,331,441) in view of Sandstrom (US 6,567,163).

Regarding claim 10, Balch discloses a microplate comprising an array of wells arranged in rows and columns, wherein the bottom of each well is a microarray substrate(fig 1a, 4, 11,&15, col. 4 lines 5-64 especially lines 60-64 , col. 6 lines 10-17). Balch fails to specifically disclose that the substrate has oriented flow-through channels.

Sandstrom (US 6,567,163) discloses that it was known in the art at the time of the invention to have a microarray substrate be provided with oriented flow-through channels for the flow of chemical and reagent for the microarray preparation, hybridization, labeling and etc.(see col. 19 lines 53 – col. 20 line 49, especially col. 20 lines 31-49).

In view of Sandstrom, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the microarray substrate comprise flow-

Art Unit: 1797

through channels as taught by Sandstrom since, Sandstrom discloses that having flow through channel allow for the flow of chemical, reagent and or sample in the microarray.

Regarding claim 12, the combined reference as applied to claim 10 above discloses the microplate according to claim 10, wherein at least the upper surface of the microplate and the inner side of the wells is non-reflecting (the microplate is made of plastic and some plastics are non-reflecting)

Regarding claim 14, the combined reference as applied to claim 10 above discloses the microplate according to claim 10, wherein all substrates are substantially located in the same virtual plane (see fig 1,4,11 &15, abs).

Regarding claim 15, the combined reference as applied to claim 10 above discloses the microplate according to claim 10, wherein the substrates are incorporated in the plate by moulding, glueing, thermal bonding or the like (see col. 6 lines 14-16).

13. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balch et al. (US 6,331,441) in view of Sandstrom (US 6,567,163) as applied to claim 10 above, and further in view of Tretiakov et al (WO 00/61797).

Art Unit: 1797

Regarding claim 11, the combination as applied to claim 10 above discloses the microplate according to claim 10. However, the combination fails to disclose that each well has a conical shape.

Tretiakov et al (WO 00/61797) discloses that it is known in the art for wells in a microplate to be conically shaped (see page 5 lines 29 -34).

In view of Tretiakov, it would have been obvious to one having ordinary skill in the art to have the wells in the microplate of the combined reference be conically shaped, since Tretiakov states that such a modification of the well enables the positioning of the entire multiwell plate into the heat block (see page 5 line 34 –page 6, line 1).

14. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balch et al. (US 6,331,441) in view of Sandstrom (US 6,567,163) as applied to claim 10 above, and further in view of Kasman (US 5,459,300).

15. Regarding claim 13, the combination as applied to claim 10 above discloses the microplate according to claim 10 wherein the substrates of the wells are substantially located in the same virtual plane. However, the combination fails to disclose that the microplate comprises a skirt having a lower side, wherein the lower side of the skirt is located in the same virtual plane or at a higher level.

Kasman (US 5,459,300) discloses that it was well known in the art at the time of the invention to have a microplate with a skirt (34, called flanges) having a lower side

Art Unit: 1797

where the lower side of the skirt is located in the same virtual plane as the bottom of the wells (see fig 2, and 4).

In view of Kasman, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the microplate of the combined reference comprise a skirt having a lower side, since such a modification would aid in securing the microplate to the heat block.

16. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balch et al. (US 6,331,441) in view of Sandstrom (US 6,567,163) as applied to claim 10 above, and further in view of the applicant admitted prior art (APA).

Regarding claim 16, the combination as applied to claim 10 above discloses the system according to claim 10. The combination fails to specifically disclose that the substrate is made of a metal oxide, preferably an aluminium oxide.

The applicant admits that it is known in the art for an array substrate to be made of a metal oxide such as aluminium oxide (see applicant's current application [0002]).

In view of the applicant admitted prior art, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the substrate of the combined reference be made of metal oxide, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability

Art Unit: 1797

for the intended use as a matter of obvious design choice.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tretiakov et al (WO 00/61797) in view of Balch et al. (US 6,331,441) and Sandstrom (US 6,567,163) as applied to claim 1 above, and further in view of Ginot et al (WO 98/41874).

Regarding claim 18, the combination as applied to claim 1 above discloses the system of claim 1 for conducting high throughput screening tests, comprising a system according to claim 1. However, the combination fails to disclose that the system/apparatus further comprises a device for linearly moving the incubation device along a plurality of stations including a station for loading a microplate into the incubation device, a station for dispensing a liquid into the wells of the microplate, and a reading station for individually illuminating each substrate of the microplate, wherein a device is provided for moving the incubation device with the microplate with respect to the reading station in mutually perpendicular directions.

Ginot (WO 98/41874) discloses the device for linearly moving another device along a plurality of station (see abs.).

In view of Ginot, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the system of the combined reference further comprise a device for linearly moving the incubator along a plurality of stations as

Art Unit: 1797

disclosed by Ginot since such a modification would enable automatic processing of the samples in the incubator.

Additionally, the phrase “for linearly moving the incubation device along a plurality of stations including a station for loading a microplate into the incubation device, a station for dispensing a liquid into the wells of the microplate, and a reading station for individually illuminating each substrate of the microplate, wherein a device is provided for moving the incubation device with the microplate with respect to the reading station in mutually perpendicular directions” is an intended use of the device and does not further limit the claim. Furthermore, the device of the combination above is capable of the applicants’ intended use (linearly moving the incubator along a plurality of processing station).

Allowable Subject Matter

17. Claim 5 is objected to as being dependent upon a rejected base claim (claim 1), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

18. The following is a statement of reasons for the indication of allowable subject matter: The prior art alone or in combination fails to disclose a system for conducting bioassays wherein the heat block, the circumferential wall and a bottom wall of the

Art Unit: 1797

incubation device encloses an air chamber having a connection for external vacuum/pressure system and a drain connection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANTA G. DOE whose telephone number is (571)270-3152. The examiner can normally be reached on Mon-Fri 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Walter D. Griffin/
Supervisory Patent Examiner, Art
Unit 1797

GSD